

Generic Name: Somatropin, somapacitan-
beco (adult)

Therapeutic Class or Brand Name: Growth
Hormone (adult)

Applicable Drugs (if Therapeutic Class):
Genotropin, Humatrope, Norditropin, Nutropin
AQ, Omnitrope, Saizen, Serostim, Sogroya,
Zomacton, Zorbtive

Preferred: Genotropin, Norditropin

Non-preferred: Humatrope, Nutropin AQ,
Omnitrope, Saizen, Serostim, Sogroya
Zomacton, Zorbtive

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 5/20/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

- I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:
 - A. Growth hormone deficiency and ONE of criteria 1 OR 2 is met:
 1. One pituitary hormone deficiency (other than growth hormone) requiring hormone replacement (such as TSH, ACTH, gonadotropins, and ADH) AND both of the following criteria a AND b are met:
 - a) At least one known cause for pituitary disease or a condition affecting pituitary function, including pituitary tumor, surgical damage, hypothalamic disease, irradiation, trauma, panhypopituitarism, or infiltrative diseases (histoplasmosis, Sheehan syndrome, autoimmune hypophysitis, or sarcoidosis) is documented.
 - b) ONE growth hormone provocative stimulation test (with insulin, levodopa, arginine, propranolol, clonidine, or glucagon) with a measured peak level of less than 5 ng/ml.
 2. Three pituitary hormone deficiencies (other than growth hormone) requiring hormone replacement AND an IGF-1 level below 80 ng/ml.
 - B. Short Bowel Syndrome and criteria 1 through 3 are met:
 1. Ability to ingest solid food.
 2. Dependent on parenteral nutrition at least five days per week to provide at least 3,000 calories per week.
 3. Chart notes to indicate dietary needs and goals have been addressed.
 - C. AIDS Wasting Syndrome and criteria 1 through 4 are met:
 1. Documented diagnosis of AIDS.
 2. Patient must be taking antiretroviral medications.

3. Documented weight loss of at least 10% from baseline weight OR a body mass index (BMI) of less than 20.
 4. Documentation that the patient has had an adequate nutritional evaluation and has failed to respond adequately to a high calorie diet.
- II. Treatment must be prescribed by or in consultation with an endocrinologist, gastroenterologist, or infectious disease specialist.
- III. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Acute Critical Illness due to complications following open heart surgery, abdominal surgery, or multiple accidental trauma, or those with acute respiratory failure.
- Active Malignancy.
- Active Proliferative or Severe Non-Proliferative Diabetic Retinopathy.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- The quantity is limited to a maximum of a 30 day supply per fill.

APPROVAL LENGTH

- **Authorization:**
 - Short bowel syndrome: One time for up to 4 weeks.
 - AIDS related wasting: Up to 12 weeks.
 - Growth hormone deficiency: Up to 12 months.
- **Re-Authorization:**
 - Short bowel syndrome: N/A
 - AIDS related wasting: An additional 12 weeks of therapy may be approved in patients who still meet current medical necessity criteria and demonstrate weight gain with the initial 12 weeks of therapy.
 - Growth hormone deficiency: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

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2. Genotropin. Prescribing Information. Pfizer; April 2019. Available at: <http://labeling.pfizer.com/ShowLabeling.aspx?id=577>.
3. Humatrope. Prescribing Information. Eli Lilly; October 2019. Available at: <http://uspl.lilly.com/humatrope/humatrope.html#pi>.
4. Norditropin. Prescribing Information. Novo Nordisk; March 2020. Available at: <http://www.novo-pi.com/norditropin.pdf>.
5. Nutropin AQ. Prescribing Information. Genentech; December 2016. Available at: http://www.gene.com/download/pdf/nutropin_aq_PI.pdf.
6. Omnitrope. Prescribing Information. Sandoz; June 2019. Available at: <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=58d84ffa-4056-4e36-ad67-7bd4aef444a5>.
7. Saizen. Prescribing Information. EMD Serono; February 2, 2022. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ab750de2-3eda-411a-924e-00c499eda39b>
8. Serostim. Prescribing Information. EMD Serono; June 2019. Available at: http://www.emdserono.com/ms.country.us/en/images/Serostim_PI_tcm115_140011.pdf.
9. Zomacton. Prescribing Information. Ferring Pharmaceuticals; July 2018. Available at: <https://d2hu1op93domjx.cloudfront.net/wp-content/uploads/sites/12/2016/02/24085312/2009055382-Zomacton-PI-Rev.-07.2018.pdf>.
10. Zorbtive. Prescribing Information. EMD Serono; February 2022. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c04b1b2c-5484-4a5d-887a-3f7ace8388a1>.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.